REGULATION OF TRANSGENIC ARTHROPODS, AND OTHER TRANSGENIC INVERTEBRATE PLANT PESTS

Introduction

This following explains the procedures associated with the permitting process for transgenic arthropods and other transgenic invertebrate plant pests. The current Federal regulations governing the permitting of transgenic organisms under the Federal Plant Protection Act of June 2000, 7 USC 7701-7772, are described in 7 CFR Part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." The Code of Federal Regulations may be found at the following internet website: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html

USDA, APHIS is obligated by statute and regulation to evaluate the potential impact to plants and the environment of transgenic organisms proposed for release into the environment that are or may become plant pests. This evaluation process begins with a determination of jurisdiction: Does the proposed introduction involve a "regulated" article as defined in 7 CFR Part 330 or 340 under the Plant Protection Act? If it is determined that APHIS does not have authority to regulate the particular article, then the process is finished and the applicant is so informed. When it is determined that APHIS has jurisdiction, then the evaluation proceeds to an assessment of the potential risks of the proposed introduction. In some circumstances, the organism or activity may already have been assessed and determined to be of no risk to plants or the environment. This may be the case for previously permitted similar organisms, or for certain activities with transgenic organisms categorically excluded from National Environmental Policy Act (NEPA) analysis listed in the NEPA Implementing Procedures for APHIS in 7 CFR Part 372. If the activity is not within these categories, the assessment is then conducted in two phases: first, an examination of the risks associated with the introduction of a nontransgenic form of the proposed species is conducted, and the second is an examination of the potential for additional risks associated with the introduction of the transgenic form. When risks are identified, ways to manage or mitigate the risk may then be proposed.

If it is determined that the proposed introduction of the candidate organism represents a significant risk to agricultural crops or the environment and cannot be permitted, the applicant is so informed. When this is not the case, an environmental assessment (EA) document may be prepared under NEPA and Council on Environmental Quality (CEQ) guidelines as described in 7 CFR Part 372. The EA document describes the potential impacts of the introduction on the environment and recommends either a finding of no significant impact (FONSI) or the preparation of an environmental impact statement (EIS). The availability of the EA and docket location are announced in the Federal Register and the public is given 30 days to comment on the EA. The docket is reviewed by APHIS and the public comments are considered for subsequent decisions and the EA may be rewritten taking public comments into consideration. When a FONSI is possible, it is prepared and a permit can then be issued. When the EIS alternative is chosen, the decision to issue or deny a permit is not made until after the EIS is prepared and the public comments are fully considered.

Jurisdiction

Federal regulations (7 CFR Part 340) under the authority of the Plant Protection Act of 2000, http://www.aphis.usda.gov/ppq/plantact/, defines a plant pest as "any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses; or any organisms similar to or allied with any of the foregoing; or any infectious substances which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants." The regulatory process concerning the introduction of plant pests involves the analysis of potential risk to the environment of a proposed introduction. For organisms that are not transgenic, the process is governed by 7 CFR

Part 330.

In the case of transgenic organisms, 7 CFR Part 340 authorizes APHIS to regulate the "introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests". To import, move interstate, or release a genetically engineered organism or product into the environment, a permit must be obtained from USDA, APHIS if the organism has been altered or produced through genetic engineering from a donor, vector, or recipient organism belonging to any genera or taxa listed in 7 CFR § 340.2 and meets the definition of plant pest, or is an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which APHIS determines is a plant pest, or has reason to believe is a plant pest.

The authority for 7 CFR Part 372, APHIS NEPA is 42 U.S.C. 4321. The § 372.5 NEPA implementing procedures define actions normally requiring environmental assessments as: "(b)(4) Approvals and issuance of permits for proposals involving genetically engineered or nonindigenous species, except for actions that are categorically excluded..."; and "(b)(5) Research or testing that: (i) Will be conducted outside of a laboratory or other containment area (field trials, for example)...". Categorically excluded actions in § 372.5 are defined as: "(c)(2) Research and development activities. (i) Activities that are carried out in laboratories, facilities, or other areas designed to eliminate the potential for harmful environmental effects—internal or external—and to provide for lawful waste disposal"; and "(c)(3) Licensing and permitting. (ii) Permitting, or acknowledgment of notifications for, confined field releases of genetically engineered organisms and products". An activity that been previously determined to have no significant impact on the environment may also be excluded from further NEPA analysis.

Exceptions to categorically excluded actions include: "(d)(4) When a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues".

Evaluation of the Nontransgenic Form Proposed for Introduction
The organism before its genetic transformation may have been indigenous or nonindigenous to the United States, and either phytophagous and thus, an actual or potential direct plant pest, or a nonphytophagous predator, parasite, or competitor of plant pests or beneficials and thus, potentially an indirect plant pest. APHIS, PPQ, Biological Assessment and Taxonomic Support (BATS) requires an application for a permit to contain specific information for a permit to release actual or potential plant pests. The application form is PPQ Form 526, "Application for Permit to move Live Plant Pests or Noxious Weeds". This form, instructions for preparing it, and frequently asked questions may be found at: http://www.aphis.usda.gov/ppq/permits/

Evaluation of the Transgenic Form
The evaluation process must consider whether the genetic changes to the organism proposed to be released have altered the risks associated with the unmodified organism. This information is requested on USDA, APHIS, Biotechnology, Biologics, and Environmental Protection Application for Permit or Courtesy Permit Under 7 CFR 340, Form 2000, available at: http://www.aphis.usda.gov/forms/. The information requested for genetically engineered organisms or products includes the following:

a. Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article.
b. A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the nonmodified parental organism (e.g., morphological or structural characteristics, physioloigical activities and

processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism [integrated or extra chromosomal], products and secretions, and growth characteristics).
c. A detailed description of the molecular biology of the system (e.g., donor-recipient-vector), which is or will be used to produce the regulated article.
d. Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced.
e. A detailed description of the purpose of the introduction of the regulated article, including a detailed description of the proposed experimental and/or production design.
f. A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country or origin and in the United States to prevent contamination, release, and dissemination in the production of the following: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article.
g. A detailed description of the intended destination (including final and all intermediate destinations), uses, and or/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trail location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).
h. A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.
i. A detailed description of the proposed method of final disposition of the regulated article.

When an application is received, it is evaluated for completeness for the purpose of doing a risk assessment. If it is found deficient, the applicant is informed what information is needed and time is allowed to provide the information. The main purpose of the risk assessment is to determine if genetic alteration changes ecological or environmental properties of the organism. Such potential risks associated with the release of a transgenic arthropod or other invertebrate could include displacement of native populations, change in host or prey utilization, change in distribution, effects on endangered or threatened species, transfer of DNA to other organisms, or, if one of the characteristics of the transgenic arthropod was increased resistance to herbicides or pesticides, subsequent increased usage of such chemicals.

A confined field trial is where the candidate arthropod is prevented from becoming established and spreading. Confinement may be by physical barriers such as screen cages, pesticides, cultural control, and biological measures such as induced sterility or pheromone traps. Confined field tests can provide important information before unconfined release is requested and may be useful to observe changes in biology, ecology, and behavior of the transgenic form compared to the parental form. References for containment procedures are the following: Arthropod Containment Guidelines by the American Committee on Medical Entomology of the American Society of

Tropical Medicine and Hygiene:
http://www.astmh.org/subgroup/acgdraft.pdf

and

NIH Guidelines for Research Involving Recombinant DNA molecules:
http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html